

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 5, 2020

Bridget Peterson Regulatory Specialist II Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102

Subject: PRIA Label Amendment – Adding Public Health Pests

Product Name: Virasept

EPA Registration Number: 1677-226

Application Date: 08/16/2019 Decision Number: 554426

Dear Ms. Peterson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Enclosure: Stamped Label

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P)

Office of Pesticide Programs

Steven Inydornan

ACCEPTED

02/05/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 4077 2000

1677-226

Virasept

Ready-to-Use

One-Step Detergent / Bactericide / Tuberculocide / Fungicide / Virucide* / Deodorizer

Broad-Spectrum Disinfectant / Hospital Use Disinfectant / Sterilant / Biofilm Bactericide[†]

†Pseudomonas aeruginosa and Staphylococcus aureus

Hospitals – Nursing Homes – Institutions – Schools – Daycare Centers – Restaurants – Food Service – Beverage and Food Processing Plants

ACTIVE INGREDIENTS:

Hydrogen Peroxide	3.130%
Octanoic Acid	0.099%
Peroxyacetic Acid	0.050%
OTHER INGREDIENTS:	96.721%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER / PELIGRO

(Note to reviewer: First aid statements must be located on the front panel to be consistent with 40 CFR)

(See [back], [side], [inside], [other] [fold-out] [booklet] [hang tag] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [precautionary statements] [and] [storage and disposal] [container handling and disposal])

(See [front] [top] [label] [panel] for [precautionary statements] [and] [first aid]

(Please [refer to] [see] reference sheet for [additional] [directions for use] [information])

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes irreversible eye damage. Do not get in eyes or on clothing. Wear goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL-FREE: 1-800-328-0026 OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

ENVIRONMENTAL HAZARDS (for containers greater than 5 gallons):

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DISINFECTION / CLEANING / DEODORIZING DIRECTIONS:

For hospital disinfection, including disinfection of biofilm on surfaces, deodorizing and cleaning of hard, non-porous surfaces, apply *Virasept* with a coarse trigger sprayer, cloth, mop, brush, scrubber, or by soaking to thoroughly wet surface. Allow surface to remain visibly wet for at least 4 minutes. Remove solution with a mop, cloth, sponge, or vacuum pickup or allow to air dry. For visibly soiled areas, a precleaning step is required. Thoroughly rinse food contact surfaces with potable water.

<u>Disinfection with sporicidal activity against [Clostridioides difficile, formerly known as]</u> Clostridium difficile

Virasept kills and/or inactivates spores of [Clostridioides difficile, formerly known as] Clostridium difficile on hard, non-porous surfaces in 10 minutes. Apply **Virasept** with a coarse trigger sprayer, cloth, mop, brush, scrubber, or by soaking until surface is visibly wet.

SPECIAL LABEL INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST [CLOSTRIDIOIDES DIFFICILE, FORMERLY KNOWN AS] CLOSTRIDIUM DIFFICILE SPORES PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

CLEANING PROCEDURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths. **INFECTIOUS MATERIALS DISPOSAL:** Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

[DISINFECTION OF BACTERIA[†] IN A BIOFILM]

TO DISINFECT IANDI IKILLI BACTERIA IN BIOFILM ON HARD. NON-POROUS SURFACES:

Virasept can be used to kill bacteria in a biofilm (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) on pre-cleaned hard, non-porous surfaces. Apply **Virasept** [with a [coarse trigger sprayer,] [cloth,] [mop,] [brush,] [scrubber] or by [flooding] or [soaking]] so as to thoroughly wet surfaces and allow to remain visibly wet for 3 minutes. Allow to air dry or remove solution with a mop, cloth, sponge, or vacuum pickup.

For heavily soiled areas, a pre-cleaning step is required. Thoroughly rinse food contact surfaces with potable water.

TO [CLEAN] [AND] [&] [DISINFECT] [BACTERIA IN BIOFILM] [IN] WASTE WATER [HOSPITAL] [KITCHEN] [SINK] [SHOWER] [FLOOR] DRAINS:

To [kill] [disinfect] bacteria in a biofilm in waste water drains, first ensure drain is clear of any obstruction by flushing thoroughly with water. Apply the product using a [manual] [automated] [pump] foamer [device] to fill the drain until excess foam collects on the drain [top] [screen] indicating that the drain [(top to p-trap)] is full. Foam must be in contact with the drain for a period of not less than 5 minutes. Apply additional foam into the drain, if necessary, to maintain contact time. No rinse is necessary. Contact your [Ecolab] representative for information on recommended foaming equipment.

TO DISINFECT [AND] [KILL] BACTERIA IN BIOFILM ON PRE-CLEANED, NON-CRITICAL INSTRUMENTS:

Virasept can be used to kill bacteria in a biofilm (*Pseudomonas aeruginosa* and *Staphylococcus aureus*) on pre-cleaned, hard non-porous surfaces of [reusable] non-critical stainless steel instruments [(not for use on flexible or semi-rigid endoscopes unless recommended by the instrument manufacturer)].

Reusable surgical instruments must be thoroughly cleaned and free of visible soil before treatment. Fully immerse or thoroughly wet instruments in *Virasept* solution (do not dilute). For hollow instruments, clean and rinse lumens prior to filling with *Virasept*. Allow to remain wet for 3 minutes. Remove and thoroughly rinse instruments.

TO DISINFECT PRE-CLEANED, NON-CRITICAL INSTRUMENTS:

Virasept can be used to disinfect pre-cleaned, hard non-porous surfaces of [reusable] non-critical stainless steel instruments [(not for use on flexible or semi-rigid endoscopes unless recommended by the instrument manufacturer)].

Reusable surgical instruments must be thoroughly cleaned and free of visible soil before treatment. Fully immerse or thoroughly wet instruments in *Virasept* solution (do not dilute). For hollow instruments, clean and rinse lumens prior to filling with *Virasept*. Allow to remain wet for appropriate contact time ([see table]). Remove and thoroughly rinse instruments.

†Pseudomonas aeruginosa and Staphylococcus aureus

BACTERICIDAL:

Virasept is an effective one-step disinfectant against the following pathogenic bacteria at a contact time of 4 minutes [in the presence of 5% organic soil load]. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

Pseudomonas aeruginosa – ATCC 15442 Staphylococcus aureus – ATCC 6538 Serratia marcescens – ATCC 14756 Escherichia coli – ATCC 11229 Escherichia coli O157:H7 – ATCC 43895 Shigella flexneri – ATCC 9380 Enterobacter aerogenes – ATCC 13048 Acinetobacter baumannii – ATCC 19606 Listeria monocytogenes – ATCC 19117 Klebsiella pneumoniae – ATCC 4352 Klebsiella pneumoniae (KPC) – ATCC BAA-1705 Salmonella enterica – ATCC 10708 Staphylococcus aureus (MRSA) – ATCC 33592 Staphylococcus aureus (VISA) – HIP 5836 Enterococcus faecalis (VRE) – ATCC 51299 Proteus vulgaris – ATCC 33420 Legionella pneumophila – ATCC 33152

STERILANT / SPORICIDAL:

Virasept is an effective sterilant on pre-cleaned hard, non-porous surfaces such as plastics, stainless steel and glass. Virasept can be used on items such as glassware, laboratory instruments, containers, [and] [insert use sites and surfaces from Table 3]. Immerse items to be sterilized in a sufficient volume of Virasept to cover the items and fill all passages requiring treatment. Virasept is effective against Clostridium sporogenes and Bacillus subtilis endospores after a 60 minute exposure time. Surfaces must remain visibly wet for the entire exposure time to achieve effectiveness against spores. Remove the

items after 60 minutes and remove the *Virasept* solution with a clean cloth or clean sponge, rinse with sterile water and allow to air dry, or drain and allow to air dry.

TUBERCULOCIDAL:

Virasept is effective against *Mycobacterium bovis* – BCG after a 2.5 minute contact time [at ambient temperature (20-25°C) in the presence of 5% organic soil load]. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

VIRUCIDAL*:

Virasept inactivates [Norovirus (Norwalk-like virus) and] the following viruses at the contact times listed below [in the presence of 5% organic soil load]. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

4 minutes:

- *Norovirus (Feline Calicivirus tested surrogate)
- *Hepatitis B Virus (HBV)
- *Adenovirus Type 4
- *Avian Influenza A Virus

- *Rhinovirus Type 37
- *Rotavirus
- *Respiratory Syncytial Virus (RSV)

2 minutes:

*Human Coronavirus

1 minute:

*Influenza A Virus

30 seconds:

*HIV-1 (AIDS Virus)

*KILLS HIV-1 (AIDS VIRUS) and HBV (HEPATITIS B VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for the transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or HBV (Hepatitis B Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings must be worn during all cleaning of body fluids, blood, and decontamination procedures.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of *Virasept*. This cleaning may be accomplished with any cleaning solution, including this product.

CONTACT TIME: HIV-1 is inactivated after a 30 second contact time. HBV is inactivated after a 4 minute contact time.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

FUNGICIDAL:

VIRASEPT is effective against *Candida auris* and *Trichophyton interdigitale* (formerly known as *Trichophyton mentagrophytes*) (the athlete's foot fungus) at a contact time of 4 minutes [in the presence of 5% organic soil load]. **Virasept** is effective against yeast *Candida albicans* at a contact time of 5 minutes. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

SPECIAL LABEL INSTRUCTIONS FOR CLEANING PRIOR TO DISINFECTION AGAINST CANDIDA AURIS

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering.

CLEANING PROCEDURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

INFECTIOUS WASTE DISPOSAL: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

MILDEWCIDAL:

Virasept is effective against *Aspergillus niger* at a contact time of 4 minutes [in the presence of 5% organic soil load]. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

(TABLE 1 – LISTED ORGANISMS AND CONTACT TIMES)

[Virasept] [is] a hospital disinfectant, and [is] [sporicidal,] [bactericidal,] [*virucidal,] [tuberculocidal,] [and] [&] [biofilm bactericidal†]

†Pseudomonas aeruginosa and Staphylococcus aureus

BACTERIA – 4 minute contact time	
Pseudomonas aeruginosa	ATCC 15442
Staphylococcus aureus	ATCC 6538
Serratia marcescens	ATCC 14756
Escherichia coli	ATCC 11229
Escherichia coli O157:H7	ATCC 43895
Shigella flexneri	ATCC 9380
Klebsiella pneumoniae	ATCC 4352
Salmonella enterica	ATCC 10708
Proteus vulgaris	ATCC 33420
Acinetobacter baumannii	ATCC 19606
Enterobacter aerogenes	ATCC 13048
Listeria monocytogenes	ATCC 19117
Legionella pneumophila	ATCC 33152
ANTIBIOTIC-RESISTANT (STRAINS OF) BACTERIA - 4 minute contact time	
Enterococcus faecalis - [Vancomycin-resistant (VRE)]	ATCC 51299
Klebsiella pneumoniae [Carbapenemase producer (KPC)]	ATCC BAA-1705
Staphylococcus aureus - [Methicillin Resistant [MRSA]]	ATCC 33592
Staphylococcus aureus - [Vancomycin Intermediate Resistant] [VISA]	CDC HIP 5836
*VIRUSES – 4 minute contact time	
*Adenovirus Type 4	ATCC VR-4
*Norovirus [Feline Calicivirus [FCV], (Strain F-9)	ATCC VR-782
*Hepatitis B Virus [HBV] (Duck Hepatitis B)	
*Avian Influenza A Virus	ATCC VR-2072
*Rhinovirus Type 37	ATCC VR-1147
*Rotavirus (WA strain)	
*Respiratory syncytial virus (RSV)	ATCC VR-26
*VIRUSES – 2 minute contact time	
*Human Coronavirus	ATCC VR-740
*VIRUSES – 1 minute contact time	
*Influenza A virus	ATCC VR-544
*VIRUSES – 30 second contact time	
*Human Immunodeficiency Virus type 1 [HIV-1]	
YEAST – 5 minute contact time	

Candida albicans	ATCC 10231
YEAST – 4 minute contact time	
Candida auris	AR-BANK #3081
FUNGI – 4 minute contact time	
Trichophyton interdigitale (formerly known as Trichophyton mentagrophytes)	ATCC 9533
Aspergillus niger	ATCC 6275
MYCOBACTERIUM – 2 minute 30 second contact time	
Mycobacterium bovis [(BCG)] [(TB)]	BCG 454C150
ENDOSPORE – 10 minute contact time	
Clostridioides difficile (formerly known as Clostridium difficile)	ATCC 700792
ENDOSPORE – 60 minute contact time	
Clostridium sporogenes	ATCC 3584
Bacillus subtilis	ATCC 19659
BACTERIAL BIOFILM – 3 minute contact time on surfaces	
Pseudomonas aeruginosa (in a biofilm)	ATCC 15442
Staphylococcus aureus (in a biofilm)	ATCC 6538
BACTERIAL BIOFILM – 5 minute contact time as a foam	
Pseudomonas aeruginosa (in a biofilm)	ATCC 15442
Staphylococcus aureus (in a biofilm)	ATCC 6538
STERILANT – 60 minute contact time	
Clostridium sporogenes	ATCC 3584
Bacillus subtilis	ATCC 19659

(MARKETING CLAIMS - can be used partially or in their entirety)

Virasept is a patented ready-to-use, Detergent-Disinfectant, Virucide, Bactericide, Biofilm Bactericide[†], Tuberculocide and Fungicide that delivers effective cleaning, disinfecting and malodor control. The unique chemistry is formulated for use in daily maintenance programs and will not harm fixtures.

†Pseudomonas aeruginosa and Staphylococcus aureus

GENERAL CLAIMS

- Virasept cleans and disinfects finished floors, sinks and tubs.
- Virasept provides non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- Virasept is effective yet economical.
- Virasept improves labor results by effectively controlling malodors.
- Virasept will not leave grit or soap scum.
- Virasept disinfects, cleans and deodorizes surfaces in rest rooms and toilet areas, garbage cans, and other listed places where bacterial growth can cause malodors.
- Virasept effectively cleans, disinfects and deodorizes hard, non-porous surfaces in hospitals, medical, dental and other health facilities.
- Virasept effectively cleans, disinfects and deodorizes bed rails, wheelchairs, wash basins, bed pans and non-critical medical equipment surfaces in hospitals (medical and healthcare) facilities. This product is not for use as a medical device sterilant or high level disinfectant.
- Virasept is effective against methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus faecalis (VRE)
- Disinfectant activity with pleasant fresh scent (with pleasant green apple fragrance).
- Formulated with patented corrosion inhibitors.
- Virasept is gentle on fixtures.
- Virasept cleans and disinfects in one labor saving step.
- Virasept's non-corrosive formula is compatible with most health care surfaces.
- Effective in 4 minutes against the bacteria and viruses listed [on the label] [in Table 1].

CROSS-CONTAMINATION CLAIMS

- [Aids in reducing] [aids in the reduction of] cross-contamination between treated surfaces
- [Can help] [Helps] Reduce[s] the risk of cross-contamination between treated hard, non-porous surfaces
- [Can help] [Helps] [Reduce][s] cross-contamination between treated hard non-porous surfaces [in the] [kitchen] [school] [classroom] [bathroom] [restroom] [in hospitals] [in healthcare settings] [in public buildings] [in long term care facilities] [household] [office] [work] [facility] [building]
- Formulated to aid in the reduction of cross-contamination between treated, hard, non-porous surfaces [in the] [home] [schools] [institutions] [and] [industry] [in hospitals] [in healthcare settings] [in public buildings] [in long term care facilities]
- For use in critical care areas [where reducing the hazards of cross-contamination between treated surfaces is of prime importance]

CONTACT TIME CLAIMS

- Bactericidal [disinfection] [efficacy] [kill] in [four] [4] minutes[¥]
- Disinfects in [four [4] [minutes] *
- [Effective against] [kills] [insert organism(s) from Table 1] in [just] [insert contact time] minute[s]
- Kills [most] [bacteria] [viruses] in [four] [4] minutes[¥]
- Kills Norovirus in [one] [1] [minute] [sixty] [60] [seconds]
- Kills [Tb] [tuberculosis] in 2 minutes 30 seconds
- Tuberculocidal [disinfection] [efficacy] [kill] in 2 minutes 30 seconds
- *Virucidal [disinfection] [efficacy] [kill] in [4] [four] minutes
- Kills Candida albicans in [5] [five] minutes
- Kills [Candida auris] in [four] [4] [minutes]
- Effective in 4 minutes against the bacteria and viruses listed [on the label] [in Table 1] *

*Does not apply to *C. difficile* or *C. albicans*

EFFICACY AND ORGANISM CLAIMS

- Broad-spectrum [hospital] [efficacy] [cleaner] [disinfectant]
- Disinfects [Kills] odor causing bacteria
- Disinfects [Kills] [the] [cold] [and] [&] [flu] virus[es]
- Effective against [insert organism(s) from Table 1] in [listed contact time]
- Effective against flu virus[es]
- Effective against non-enveloped viruses of concern [such as] [*Feline Calicivirus] [*FCV] [and] [&] [*Norovirus] [and] [&] [*Rhinovirus] [and] [&] [*Rotavirus]
- Effective in [insert contact time] against [insert organism(s) from Table 1]
- Effectively disinfects common hard, non-porous [household] [hospital] surfaces
- Exhibits effective *virucidal activity; kills [*Influenza A virus (representative of the common flu virus)], [(*Influenza A (H5N1)] [and] [&] [*Rhinovirus (common cold)] [and] [&] [*Feline Calicivirus or FCV (surrogate organism for Human Norovirus)]
- Virasept is a hospital disinfectant
- [Kills] [effective against] [wipes-out] [eliminates] a minimum of 99.9% of [insert organism(s) from Table 1]
- [Kills] [effective against] [MRSA] [Methicillin resistant *Staphylococcus aureus*]
- [Kills] [effective against] [yeast] [C. auris] [Candida auris] [and] [C. albicans] [Candida albicans]
- Kills *Influenza A virus on hard, non-porous surfaces
- Meets surface disinfection recommendations from OSHA Bloodborne Pathogen Standard
- On hard, non-porous [inanimate] [environmental] surfaces, Virasept kills the following organism[s][:]
 [insert organism(s) from Table 1]
- Virasept [is] effective against the following microorganism[s] on hard, non-porous surfaces when used as directed[:] [insert organism(s) from Table 1]
- Virasept is effective against methicillin-resistant Staphylococcus aureus (MRSA) and vancomycinresistant Enterococcus faecalis (VRE)
- Virasept is effective against Avian Influenza virus.
- Virasept is effective against Hepatitis B Virus.
- Virasept is tuberculocidal.
- Kills 99.9999% of bacteria Pseudomonas aeruginosa and Staphylococcus aureus in biofilms on a hard, non-porous surface
- Reduces 99.9999% of bacteria Pseudomonas aeruginosa and Staphylococcus aureus growing in biofilms
- Formulated to kill 99.9999% of bacteria Pseudomonas aeruginosa and Staphylococcus aureus in biofilms
- Kills biofilm bacteria Pseudomonas aeruginosa and Staphylococcus aureus
- Penetrates biofilms, killing the bacteria *Pseudomonas aeruginosa* and *Staphylococcus aureus* [living there]
- Bacteria tested as a biofilm include Pseudomonas aeruginosa and Staphylococcus aureus
- Kills 99.9999% of bacteria *Pseudomonas aeruginosa* and *Staphylococcus aureus* in biofilms in waste water drains (shower, sink, and floor drains)
- Kills 99.9999% of bacteria in biofilms on pre-cleaned hard, non-porous surfaces of [reusable] noncritical stainless steel instruments
- Disinfects pre-cleaned hard, non-porous surfaces of [reusable] non-critical stainless steel instruments [prior to [terminal] sterilization processes]

GENERAL CLAIMS

- Antibacterial
- Antimicrobial
- Bactericidal
- Tuberculocidal
- *Virucidal
- Biofilm Bactericidal[†]
- [Designed] [built] for everyday [disinfecting] [cleaning messes]

- Designed for [hospital] [healthcare] [long-term care facility] use
- [Easy enough] for everyday use
- Easy on surfaces
- [Every day] [every room] disinfectant on hard, non-porous surfaces
- [Easy] [/effective]
- For [healthcare] [hospital] [long-term care facility] use
- For use in [hospital] [healthcare] settings [as a multi-purpose disinfectant cleaner]
- Hospital [cleaner] [and] [&] disinfectant
- Leaves no [dull] [sticky] residue
- Leaves [kitchens] [schools] [classrooms] [bathrooms] [restrooms] [hospitals] [healthcare settings]
 [public buildings] [long term care facilities] [households] [offices] [work] [facilities] [buildings]
 [bathrooms] smelling clean
- Leaves surfaces virtually streak-free
- No added [dyes]
- No mixing [and/or fuss]
- No mixing, measuring, or rinsing required
- No [mixing] [mess] [fuss] [muss]
- No rinsing required [(non-food contact surfaces only)]
- No [sticky residue] [formula]
- Non-abrasive
- [This product] [Virasept] is a [hospital use] [germicidal] [disinfectant] [and] [&] [cleaner] [and] [&] [deodorant] [odor counteractant] [odor neutralizer] designed for general cleaning [and] [&] disinfecting [and] [&] [deodorizing] [of] hard, non-porous [inanimate] surfaces
- Formulated with patented corrosion inhibitors.
- Virasept is gentle on fixtures.

†Pseudomonas aeruginosa and Staphylococcus aureus

ONE-STEP CLAIMS – does not include claims where pre-cleaning of surfaces is required, such as disinfection against bacteria in biofilm, *C. diff*, and *C. auris*.

- Cleans [and] [&] disinfects [common] hard, non-porous surfaces [in one[1]-step]
- [Cleans] [disinfects] [deodorizes] [in one[1]-easy step] on hard, non-porous surfaces when the use directions for Disinfection are followed
- [Cleans] [and] [&] [deodorizes] [and] [&] [disinfects] [eliminates odors] [all] [in one[1]] [easy] [step] when the use directions for Disinfection are followed
- Disinfects [as it cleans] [and] [&] [scrubs] [in one[1]] [easy] [step] when the use directions for Disinfection are followed
- Disinfects while cleaning[-up] stubborn messes
- [Dual-action] cleans up stubborn messes while it disinfects
- Easy [and] [&] convenient disinfecting
- [Easily] [effectively] [conveniently] [cleans] [and] [&] [disinfects]
- Effective in the presence of 5% organic soil contamination [(pre-clean for [*HIV-1]/[*HBV])
- Effectively disinfects in the presence of organic soil (5% blood serum) [(pre-clean for [*HIV-1]/ [*HBV])
- Multi-purpose [cleaner] [and] [&] [disinfectant]
- [One][1]-[labor saving] step
- One[1]-step [cleaning] [and] [&] [disinfecting] [and] [&] [deodorizing] when the use directions for Disinfection are followed
- [One[1]-step] [hospital] cleaner [and] [&] disinfectant when the use directions for Disinfection are followed
- One[1]-step disinfectant [and] [&] cleaner that is effective against a broad spectrum of [bacteria]
 [organisms] when the use directions for Disinfection are followed
- Optimize[s] staff productivity [with [one][1]-easy step]
- Proven one[1]-step disinfectant [and] [&] cleaner [which is effective in the presence of 5% organic soil contamination] when the use directions for Disinfection are followed
- Ready-to-use [cleaner] disinfectant [cleaner]
- Save[s] time

• [This product] [Virasept] is a [one][1]-step hospital use [germicidal] [disinfectant] [and] [&] cleaner [and] [&] [deodorant] [odor counteractant] [odor neutralizer] designed for general cleaning [and] [&] disinfecting [and] [&] [deodorizing] of hard, non-porous inanimate surfaces when the use directions for Disinfection are followed

- [This product] [Virasept] is [an effective] [bactericidal] [*virucidal] [tuberculocidal] product in the presence of organic soil (5% blood serum) against [insert organism(s) from Table 1].
- Versatile [cleaner] disinfectant [cleaner]
- Virasept cleans and disinfects in one labor saving step.

ODOR CLAIMS

- Deodorizer
- [Deodorizes] [and] [&] [disinfects] as it cleans
- [Doesn't] [Don't] just mask odors [eliminate] [neutralize] them
- Eliminates [removes] odors
- Freshens [as you clean]
- [Gets rid of] [eliminates] odors
- [Helps] [eliminates] [neutralizes] odors
- [Helps] [kills] [eliminates] odor-causing bacteria
- · Kills odor causing bacteria
- Leaves a [light] [clean] [fresh] scent
- Odor [counteractant] [elimination] [neutralizer] [neutralization] [neutralizing]
- [This product] [insert product name] will deodorize hard, non-porous surfaces [such as] [insert object(s)/surface(s) from Table 3] [where obnoxious odors may develop] [and other places bacteria growth can cause malodors]
- Tough on odor

USE SITES/PROCESSES/STAINS/SOILS

- [Cleans] [and] [disinfects] the following surfaces[:] [insert object(s)/surface(s) from Table 3]
- Cleans [the following soils:] [insert stain(s)/soil(s) from Table 5]
- Compatible with most hard, non-porous surfaces
- [Designed to be] compatible with [hospital] [equipment] [surfaces]
- Disinfect, clean and deodorize hard, non-porous surfaces such as[:] [insert materials from Table 4]
- Effective [disinfecting] [and] [&] [cleaning] for use in [insert use site(s) from Table 2]
- Kills [removes] [bacteria] [viruses*] [germs] from [insert object(s)/surface(s) from Table 3]
- Kills [removes] [bacteria] [viruses*] [germs] from [insert materials from Table 4]
- For general [cleaning] [and] [&] [disinfecting] hard, non-porous surfaces
- For hard, non-porous surfaces [floors]
- Suitable for use on flexible, [hard], non-porous surfaces
- For [medical] [hospital] [dental] [clinical] equipment
- For [terminal] [discharge] cleaning
- For use on hospital surfaces [such as:] [insert object(s)/surface(s) from Table 3]
- Formulated for use in daily maintenance programs [with a balance of detergents [and] [&] malodor counteractants that deliver effective cleaning, disinfecting and malodor control]
- Good for use on common healthcare surfaces
- Great for cleaning around the toilet
- [Great] for [the] [school(s)] [and] [&] [classroom(s)]
- Great for [the] [your] [use in] [insert use site(s) from Table 2]
- Great for [the] [your] [use on] [insert object(s)/surface(s) from Table 3] [insert materials from Table 4] [insert stain(s)/soil(s) from Table 5]
- Hospital [disinfectant] [disinfection] [use on] [insert object(s)/surface(s) from Table 3] [insert materials from Table 4]
- Ideal for use in [:] [insert use site(s) from Table 2]
- Ideal for use on high touch surfaces
- Virasept is recommended for use in [health care settings] [such as:] [insert use site(s) from Table 2]

Virasept can be used on other hard, non-porous surfaces [made of] [such as:] [insert objects/surfaces from Table 3]

- Virasept will effectively clean [and] [&] disinfect, when used as directed, such items as [:] [insert object(s)/surface(s) from Table 3]
- Multi-surface [cleaner] [and] [&] [disinfectant] [disinfecting] [cleaner]
- Multi-room [cleaner] [and] [&] [disinfectant] [disinfecting] [cleaner] on hard, non-porous surfaces
- · Removes dried on [blood] stains
- [Removes] [and] [or] [cleans] [insert stain(s)/soil(s) from Table 5]
- Suitable for use on flexible, hard non-porous surfaces
- [This product] [Virasept] is designed [for use] [specifically] as a [general] [non-abrasive] [cleaner] [and] [&] disinfectant [at] [in] [on] the following [areas] [sites]: [insert use site(s) from Table 2]
- [This product] [Virasept] is designed [for use] [specifically] as a [general] [non-abrasive] [cleaner] [and] [&] disinfectant [at] [in] [on] the following [objects] [and] [&] [surfaces] [:] [insert object(s)/surface(s) from Table 3]
- [This product] [Virasept] is formulated to disinfect hard, non-porous, [inanimate] [environmental] surfaces including [:] [insert object(s)/surface(s) from Table 3] [insert materials from Table 4]
- [This product] [Virasept] is safe for use [as a] [general] [non-abrasive] [cleaner] [and] [&] [disinfectant] on the following hard, non-porous materials [:] [insert material from Table 4]
- Use to [pre-clean] non-critical medical devices prior to [sterilization] [high-level disinfection]
- Use Virasept to clean [and] [&] disinfect hard, non-porous surfaces [such as] [:] [insert area from Table 31
- Virasept will not harm finished floors.

(TABLE 2 - USE SITES)

airplane[s]	dialysis [clinics] [facilit[y/ies]]	[ophthalmic] [optometry] office[s]
airport[s]	[dorms] [dormator[y/ies]]	ophthalmic offices
[ambulances] [emergency medical transport vehicles]	emergency room[s] [ERs]	orthopedic[s]
ambulatory care center[s]	[exam] [examination] [rooms]	[out-patient] [surgical] [centers] [OPSC] [clinics]
[ambulatory surgical centers] [ASC]	[eye] surgical center[s]	patient [areas] [rooms]
anesthesia [areas] [rooms]	[food service establishments] [restaurants]	pet shop[s]
animal [boarding] [hospitals] [housing] [treatment] [facilit[y/ies]]	garbage [areas] [storage]	pharmac[y/ies]
animal [life science] laborator[y/ies]	[grocery] [retail] [stores] [businesses]	[physical therapy] [PT] [areas] [rooms]
[apheresis] [blood] [milk] [plasma] [semen] donation [centers] [facilit[y/ies]]	healthcare [facilit[y/ies]] [settings]	playground[s] [equipment]
[assisted-living] [full-care] nursing homes	health club[s]	psychiatric facilit[y/ies]
[athletic] [athlete] [exercise] [recreational] facilit[y/ies]	home health care [settings]	[public] [school] bus[es]
[barber shops] [beauty salons]	hospice[s]	public [care] area[s]
boat[s]	hospital[s]	[public] restroom[s]
bus [depots] [stations]	[hotels] [lodging establishments] [motels]	[radiology] [x-ray] [areas] [rooms]
camper[s]	[institutional facilit[y/ies]] [institutions]	reception [areas]
car[s]	[intensive care] [units] [ICUs]	recovery room[s]
catter[y/ies]	isolation area[s]	rehabilitation center[s]
central service area[s]	lab[oratory][ies]	respiratory center[s]
central supply [rooms] [areas]	laundry room[s]	respiratory therapy [areas] [rooms]
[changing] [locker] room[s]	locker room[s]	restroom[s]

[childcare] [daycare] [centers] [facilit[y/ies]	lodging establishments	retail business[es]
clinic[s]	[long term care] [LTC] facilit[y/ies]	school[s]
[colleges] [universities] [college] [university]	manufacturing facilit[y/ies]	shower [rooms] [stalls]
[commercial] kitchens	[medical] clinic[s]	stable[s]
[computerized axial tomography] [CAT] lab[orator[y/ies]]	medical facility[y/es]	[surgery] [surgical] center[s]
correctional facilit[y/ies]	military installation[s]	[surgery] [surgical] room[s]
critical care unit[s] [CCUs]	non-porous hospital mattresses	taxi[s]
cruise ship[s]	nursing home[s]	train[s]
daycare[s]	[nurse's] [nursing] station[s]	transportation terminal[s]
dental [clinics] [offices]	nurser[y/ies]	universities
dialysis clinics [facilities]	office building[s]	vet[erinary] [clinics] [offices] [rooms]
[doctor's] [medical] [physician's] office[s]	[operating rooms] [ORs]	waiting [areas] [rooms]

(TABLE 3 – HARD NON-POROUS OBJECTS/SURFACES)

[air vent exteriors] [exterior surfaces of air vents]	docking station[s]	operatory light switch[es]
anesthesia [equipment] [machines]	environmental surface[s]	oxygen hood[s]
[animal] [cages] [crates]	[exam] [examination] table[s]	over-bed table[s]
apheresis machine[s]	[external surfaces of medical equipment] [medical equipment surfaces]	paddle[s]
autoclaves	[external surfaces of] ultrasound [transducers] [and] [&] probes]	pager[s]
[bathroom] [patient room] doorknob[s]	exterior of pipes	patient chair[s]
[bathroom] fixture[s] [surfaces]	feeding [and] [&] watering equipment	patient monitoring equipment
bedpan[s]	footboard[s]	phlebotomy tray[s]
bedrail[s]	garbage [areas] [bins] [cans]	phone cradle
[bedside] commode[s]	[grocery] [shopping] [carts] [handles]	[physical therapy] [PT] [equipment] [surfaces]
[bedside] table[s]	gurney[s]	plastic mattress cover[s]
[blood pressure] [BP] cuff[s]	[hair] [clippers] [dryers] [equipment] [implements] [shears]	power cord[s]
[blood pressure] [BP] monitor[s]	[handheld] [electronic] device[s]	pulse oximeter[s]
[cabinet] handle[s]	[hard, non-porous] edge[s] of privacy curtain[s]	PVC tubing
call box[es]	hard, non-porous [environmental] [hospital] [medical] surface[s]	reception [counter] [desks] [furniture] [tables]
[cardiopulmonary resuscitation] [CPR] [dummy/ies] [equipment] [training equipment]	headboard[s]	remote control[s]
cart[s]	highchairs	respirator[s]
[cellular] phone[s]	high touch [medical] surface[s]	respiratory therapy equipment
chair[s]	headboard[s]	resuscitator[s]
charging station[s]	[hospital] [patient] bed[s] [frames] [linings] [railings] [springs]	scale[s]
[child care] [infant] equipment surfaces	infant [bassinets] [cribs] [incubators] [warmers]	sequential compression device[s]
closet handle[s]	[inner] [inside of] drawer[s]	shower drain[s]
[coated] [plastic] mattress[es]	[instrument] stand[s]	shower [equipment] [fixtures] [stools]

[coated] [plastic] pillow[s]	[intravenous] [IV] [stands] [pumps] [poles]	side rail[s]
[computers] [PCs]	isolette[s]	sink drain[s]
[computer] [mobile] [public] workstation[s]	[Kendrick Extrication Device] [KED]	[slit] lamp[s]
computer mouse	kennel[s]	spine backboard[s]
computer screen[s]	keyboard[s]	stethoscope[s]
computer table[s]	laptop[s]	stool[s]
[computerized axial tomography] [CAT] equipment	light switch[es]	stretcher[s]
cord[s]	mammography equipment	support bar[s]
[counters] [countertops]	medication cart[s]	table[s]
[crash] [emergency] cart[s]	mobile device[s]	tablet[s]
dental [chairs] [counters] [equipment trays]	mobile electronic equipment	tanning bed[s]
dental curing light[s]	mouse pad[s]	toilet [fixtures] [handholds] [handles] [seats] [surfaces]
dental operatory surface[s]	[magnetic resonance imaging] [MRI] equipment	toy[s]
desktop[s]	[nail] [equipment] [implements]	traction device[s]
diagnostic equipment	nurse-call [buttons] [devices] [and] [&] [cords]	walker[s]
dialysis machine[s]	[non-porous] [hospital] mattress[es]	walls [around toilet] [in patient rooms]
[diaper] [changing] station[s]	nurse-call [buttons] [devices] [and] [&] [cords]	wash basin[s]
diaper pail[s]	[operating room] [OR] [tables] [and] [&] [lights]	wheelchair[s]
floor drain[s]	patient support and delivery equipment	x-ray equipment

(TABLE 4 – MATERIAL COMPATIBILITY)

acrylic	glazed ceramic [tile]	nickel [finish]
baked enamel surfaces	glazed porcelain	sealed porcelain
chrome	glazed tile	stainless steel
electronic surfaces	[hard] plastic [surfaces]	upholstery plastic and vinyl
Formica® [surfaces] [countertops]	laminated surface[s]	vinyl
glass	metal[s]	

[This product is compatible with the listed materials. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.]

TABLE 5 - STAINS/SOILS)

[automotive] [splattered] grease	fingerprints	pen [marks]
bathtub ring	[food] [greasy] [oily] [soils]	pencil [marks]
beverage stains	food [residues] [soils] [stains]	pet stains
bile	grease	pus
blood	grime	rust
body [fluids] [oils]	heel [marks] [scuffs]	smudges
coffee [stains]	ink [marks]	soap scum
cosmetics	laboratory [mess] [spills]	sticky food [messes] [and] [&] [or] [spills]
crayon [marks]	[mildew] [and] [&] [or] [mold] stains	tea [stains]

dead skin	mucus	tough soil[s]
diarrhea	mud	urine [stains]
dirt	other [common] [soils] [stains]	vomit
fecal matter	other organic matter	

STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER. FOOD OR FEED BY STORAGE OR DISPOSAL.

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal:

(For containers 5 gallons or less): Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons): Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(2.5 gal bladder in box): Non-refillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer box and bladder for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(Non-refillable sealed container is designed to reduce worker exposure to the concentrate. This container cannot be triple rinsed because it is a closed container. The following text will be used on this container.) Non-refillable sealed container. Do not reuse or refill this container. Wrap empty container and put in

(275 gallon, 300 gallon and 330 gallon tote): Verify that tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

EPA Reg. No. 1677-226

EPA Est.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R), 1677-TX-1 (D), 1677-IL-2 (J), 1677-GA-1 (M), 1677-WV-1 (V), 303-IN-1 (L), 58046-TX-2 (X), 5389-NC-1 (G)

Superscript refers to first letter of date code

(Manufactured) (Distributed) by: Ecolab Inc. 1 Ecolab Place St. Paul, MN 55102

Este producto puede ser patentado: www.ecolab.com/patents

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This product may be patented | Ce produit peut être breveté |

Net Contents: 1 U.S. quart (946 ml) 1 U.S. gallon (3.78 L) 2.5 U.S. gallons (9.45 L) 5 U.S. gallons (18.9 L) 275 U.S. gallons (1,041 L) 300 U.S. gallons (1,136 L) 330 U.S. gallons (1,249 L)

(Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.) (If you cannot read English, ask your supervisor for the appropriate instructions before handling this product.)

EMERGING VIRAL PATHOGENS

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to long term care professionals, food safety professionals, environmental services professionals, health care facilities, physicians, nurses, veterinarians and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). *These statements shall not appear on marketed (final print) product labels.)*

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label
Enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782),
'	Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)
Large, non-enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782),
	Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)
Small, non-enveloped virus	Feline calicivirus, Strain F9 (ATCC VR-782),
	Rhinovirus Type 37, Strain 151-1 (ATCC VR-1147)

[Virasept] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [Virasept] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.